Questions from Ranking Member Murray:

Tobacco
Flavors Compliance Policy
During your confirmation hearing, I was disappointed by your answers to questions from multiple Senators on your commitment to combatting youth tobacco use. The lack of a commitment from you followed the testimony of Mitch Zeller, Director of FDA's Center for Tobacco Products, one week earlier. Mr. Zeller refused to provide the Committee, under repeated questioning, with an update on the status of the policy announced by the Administration in September to remove all non-tobacco flavored e-cigarettes from the market until reviewed by the FDA. Rather than answer us, Mr. Zeller suggested that I and other members direct our questions to the White House. At the same hearing, Dr. Anne Schuchat, principal deputy director of the CDC, told the Committee, "We know flavors are particularly attractive to youth," and said that, if a flavored e-cigarette were permitted to remain on the market, "we believe kids will likely use whatever flavor is left."
1. If confirmed, are you committed to finalizing the flavors compliance policy the Administration announced on September 11?

Response I understand that the final compliance policy is under consideration by the Administration. I look forward to their decision. I'm not privy to that decision-making process. But I very much agree and support that aggressive action needs to be taken to protect our children. I think this is an important, urgent crisis in this country. I do not want to see another generation of Americans become addicted to tobacco and nicotine. And I believe that we need to take strong action to stop that.

2. If confirmed, are you committed to responding to questions about FDA matters instead of referring us to the White House?

Response: I will respond to questions asked of the Committee, consistent with legal an ethics requirements.

3. Do you agree with Dr. Schuchat that flavors make e-cigarettes more attractive to youth and that, if all flavors are not removed from the market, youth will shift to the flavors that remain on the market?

Response: I've seen the data suggesting that flavors are a significant effect for children using e-cigarettes and I am alarmed by those data. I think this is an important, urgent crisis in this country. I do not want to see another generation of Americans become addicted to tobacco and nicotine. And I believe that we need to take strong action to stop that.

4. As Commissioner, would you ensure the decisions FDA makes are based on the best available science?

Response: If confirmed, I commit to using science, data and the law to guide my decisions at FDA.

Youth Tobacco Use
5. All flavored tobacco products pose a threat to children. Are you committed to clearing the market of all flavored tobacco products, including menthol cigarettes and flavored cigars?

Response: I'm a lung cancer doctor, and I have seen the ravages of tobacco-related cancers. I also know youngsters who were very close to me who use e-cigarette products. I'm aware of the National Youth Tobacco Survey data. And I think this is an important, urgent crisis in this country. I do not want to see another generation of Americans become addicted to tobacco and nicotine. And I believe that we need to take aggressive action to stop that.

6. What other steps do you intend to take to combat youth tobacco use?

Response: If confirmed, I look forward to learning from many internal and external stakeholders about all the options and working with Congress to tackle this problem together. I am open to evaluating strategies that would aggressively address this epidemic. I think this is an important, urgent crisis in this country. I do not want to see another generation of Americans become addicted to tobacco and nicotine. And I believe that we need to take strong action to stop that.

7. As youth tobacco use skyrockets, the need for effective youth cessation options has become especially acute. What steps would you take to improve the availability of FDA-approved youth cessation products?

Response: Tobacco cessation and nicotine addiction and are serious problems. I see that because many of my patients want to stop smoking cigarettes. Fortunately, there's great research, much of which has been funded by Congress at NIH that's allowed us to look at this intersection between nicotine addiction, tobacco use and what we may be able to do in the future. I am very supportive of taking measures and expediting those measures to try to find out what novel products we can use to help with the tobacco cessation problem that we have. I think this is an important, urgent crisis in this country. I do not want to see another generation of Americans become addicted to tobacco and nicotine. And I believe that we need to take strong action to stop that.

Vaping-Linked Illnesses
As of November 13, more than 2,000 people have been sickened by vaping-linked lung illnesses.
8. What steps do you intend to take to combat the outbreak of vaping-linked illnesses and prevent similar outbreaks in the future?

Response: If confirmed, I look forward to immediately getting up to speed on this issue. What I now know if from press reports—that CDC and FDA are working closely with States to investigate each reported illness and death. And that they have found some common causes, but more work remains. I will continue the good work of Acting FDA Commissioner Ned Sharpless to work collaboratively with CDC and make the public aware of key findings and precautionary warnings as expeditiously as possible. I think this is an important, urgent crisis in this country. I do not want to see another generation of Americans become addicted to tobacco and nicotine. And I believe that we need to take strong action to stop that.

Nicotine Reduction
The Trump Administration now also appears to be breaking its 2017 promise to reduce the level of nicotine in cigarettes to minimally- or non-addictive levels.
9. Is FDA continuing its work towards reducing nicotine levels in cigarettes?

Response: I am not privy to the internal decision-making of the FDA. I pledge to look into this matter should I be confirmed.

10. Are you committed to moving forward with the Administration's proposal to reduce nicotine in cigarettes?

Response: I commit to using science, data and the law to guide my decision-making. If evidence suggests this is a viable option to discourage the use of tobacco products, I will pursue it.

Antibiotic resistance
The Centers for Disease Control (CDC) estimates that more than 2.8 million antibiotic-resistant infections occur in the U.S. each year, resulting in over 35,000 deaths annually. The World Health Organization's global assessment of antibiotic resistance concluded that antibiotic resistance is a "major threat to human health." There are well-established connections between antibiotic use in food production and rising antibiotic resistance in common human pathogens. Already, the CDC estimates that antibiotic resistant foodborne pathogens cause 430,000 illnesses each year in the United States.

11. Please provide your assessment of this situation and the actions that FDA intends to take to prevent animal antibiotics from being used for unlimited or excessive durations?

Response: All growth promotion indications have been removed from labeling indications, which reduced the amount of antibiotics used in animals. I would consult with careers at the Agency on additional steps FDA could take. I think this is an area that deserves attention and close monitoring of sales data and additional studies. The Agency issued grants in 2016 to study this issue and, if confirmed, would look forward to learning about the findings from these studies and the potential recommendations. I will partner with Congress, the Administration and other stakeholders moving forward on this important issue.

12. How does FDA intend to ensure that antibiotics currently available over-the-counter will not be used in excessive doses and durations that are beyond the scope of their "disease prevention" indication?

Response: If confirmed, I would partner with career staff to better understand over-the-counter utilization of antibiotics and examine any data the Agency is collecting on the issue. This is a very important issue. I believe that tracking sales data of these products will be informative and could guide evidence-based actions in the future.

13. What role do you envision for veterinarians in antimicrobial stewardship in food production?

Response: Veterinarians play a critical role in antimicrobial stewardship in food products. I understand that CVM has recognized the value of their role and has established an effective partnership with the veterinarian community to combat AMR. I look forward to partnering with appropriate stakeholders including the veterinarian community to address this important issue.

14. If confirmed, do you commit to requiring veterinarian involvement any time an antibiotic is used in an animal?

Response: I think veterinarian involvement is critical when antibiotics are prescribed to animals.

15. What is the current status of FDA and USDA joint efforts to collect data on antibiotic use in food animal production?

Response: Since I am not currently at the FDA, I do not know the current status of these efforts. However, if confirmed, I commit to looking into this issue.

16. What investments should Congress prioritize to improve data collection and antibiotic use reporting and to further improve understanding of changes in antibiotic resistance patterns?

Response: If confirmed, I would consult with experts at the Agency to discuss this issue. From my own medical experience, I believe that tracking infections, prescriptions, and product sales will provide valuable tools to track utilization and potentially partner with health care systems to better understand prescribing practices. This could guide evidence-based actions in the future.

17. Please provide an assessment of FDA's progress in implementing Guidance for Industry 209 and 213 and the Veterinary Feed Directive final rule. Please preview any expected milestones for the coming year.

Response: There are many well-documented challenges to conducting clinical trials for antibiotics; for example, finding and enrolling patients with rare drug resistant infections. The 21st Century Cures Act of 2016 granted FDA authority to establish a new regulatory pathway, Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD), to overcome challenges specific to development of new antibiotic therapies.

18. Please give your assessment of the current state of the LPAD pathway implementation.

Response: To date, two drugs have been approved in the LPAD pathway since it was authorized in 21st Century Cures in 2016. The lack of products in the antibiotic development pipeline has been a significant issue for many years and in my opinion, it is too early to assess the true impact of the LPAD pathway. My understanding is that our career staff works hard to appropriately engage with sponsors to use the appropriate regulatory tools to support development and review. Because drug development generally takes 10 years it will take some more time to understand the full effect of the program.

19. Please describe actions FDA can take to further facilitate development of new antibiotics.

Response: I believe the Agency has taken many steps to facilitate development of new antibiotics including utilizing the LPAD pathway, leveraging the flexibility of clinical trials and developing breakpoints. Diagnostics can play a critical role in stewardship and utilization so physicians could identify the appropriate drug and dosage to treat the infection. I believe that post-market surveillance and real-world evidence can play a critical role to better understanding these infections, the treatments and stewardship. If confirmed, I would be eager to engage with experts at the Agency to learn more about this critical work.

Cannabidiol (CBD)
At this time, it is unlawful to market food or dietary supplements containing cannabidiol (CBD) in interstate commerce. Under current law, for CBD to be lawfully marketed in a food or dietary supplement, FDA would have to issue a regulation allowing for the marketing of CBD in those products. FDA has said that it is exploring an approach to regulating CBD that takes into account the safety and quality of CBD-containing products. In addition, FDA has also noted the importance of preserving incentives for research and drug development. FDA has estimated that rulemaking on CBD would take three to five years.
I want to preserve FDA's role in regulating cannabis products marketed as drugs and in foods, dietary supplements, and cosmetics, as well as preserve the incentive to develop new pharmaceutical treatments. I am concerned that the FDA timeframe is too long, given the agency's concerns. It is important that FDA move as quickly as possible, without sacrificing consumer safety and the public health.

20. Will you make FDA regulation and oversight of CBD-containing products—including food, dietary supplements, drugs, and cosmetics—a top priority?

Response: Yes, if confirmed, I will make this a top priority. As you know, CBD is widely available throughout the United States. It can be purchased in many places across the country. There are open questions and knowledge gaps about these products such as: 'What is the appropriate dosage and for which health claim?' What are the potential interactions with other drugs? What are the health effects of long term usage particularly among youth. On the other hand, we need to recognize that there are potential therapeutic benefits from CBD. In fact, FDA approved a CBD-containing product for the treatment of a serious childhood seizure disorder. There are signals that CBD might be useful for other conditions. However, I am concerned about the unsubstantiated claims that CBD can be useful for conditions like cancer and Alzheimer's disease. It is important to ensure that any claims made to treat a disease are supported by the appropriate safety and efficacy data. I look forward to reviewing the data on the safety of CBD with career staff and to work with the Agency and all appropriate federal partners to determine if there is a clear and transparent pathway for consumer products (e.g. food additives and dietary supplements). I am committed to using science, data, and the law to guide all of my decisions at the FDA and working with Congress and the Administration to make the absolute best decisions for the American people.

21. Will you aggressively enforce current law against CBD products that are marketed with false or misleading claims?

Response: I am concerned about the unsubstantiated claims that CBD can be useful for conditions like cancer and Alzheimer's disease. It is important to ensure that any claims made to treat a disease are supported by the appropriate safety and efficacy data and that enforcement actions reflect this principle. I take very seriously the role of the FDA in protecting public health and ensuring consumers have accurate information to make the best decisions possible.

22. How will you preserve and enhance incentives for research and development of drugs that contain CBD and other cannabinoids?

Response: I look forward to learning more about the barriers to research and development of drugs that contain CBD and other cannabinoids. I will also work with the Drug Enforcement Agency, the National

Institute on Drug Abuse, the USDA and other relevant federal agencies to determine if there are unnecessary barriers that can be streamlined.

Compounding

In 2013, Congress enacted the Drug Quality and Security Act (DQSA), to establish a clear regulatory regime for compounded products, after a contaminated compounded injectable caused a meningitis outbreak that sickened over 800 people and killed 64 people in 2012. Since passage of the DQSA, FDA has devoted significant agency resources to implementing and enforcing its compounding-related authorities.

23. Do you commit, if confirmed, to continuing FDA's work to ensure continued access to quality compounded drugs for patients who need them and strengthen regulatory oversight to protect patients from unsafe, ineffective, and poor quality products?

Response: Yes. This is an issue of importance particularly with respect in situations where there is a shortage of a prescription drug or a patient cannot use an FDA-approved product; in other words to meet a specific medical need. If confirmed, I am committed to implementing DQSA, as intended by Congress, to both protect patient safety, and allow the safe and appropriate practice of pharmacy compounding to occur in the way that Congress intended.

Cosmetics

In December 2018, a *Reuters* investigation showed a long history of asbestos contamination in talc used for baby powders. This year, FDA has released findings from testing several products, which revealed asbestos contamination in a number of cosmetic products marketed to children and teenagers. Most recently, in October, FDA alerted consumers that Johnson & Johnson had voluntarily recalled one lot of Johnson's Baby Powder after a sample tested positive for asbestos. I am alarmed by the continued reports of asbestos contamination in cosmetic products, especially those marketed to children and teenagers. FDA must do everything it can to respond to these issues and ensure our products are safe for use.

24. Do you believe FDA needs to do more to ensure cosmetic products on the market are safe?

Response: I agree that FDA must do everything possible to ensure that consumer products under the agency's jurisdiction are free from adulterants like asbestos. If confirmed I will work with FDA staff to get quickly up to speed on this issue, and will work to address any shortcomings. I commend the agency on its work to detect these adulterated products and get them off the market.

25. What resources will you commit to continuing FDA's investigations of contamination in talc products—and to monitoring, testing, and enforcement of applicable laws and regulations governing cosmetic products?

Response: If confirmed, I will ensure that the cosmetics program prioritizes products that have demonstrated a higher level of risk to consumers. I will also commit to working with Congress and stakeholders to better understand ways that the program can be more effective in achieving its mission.

26. What authorities and resources does FDA need to ensure the safety and quality of cosmetic products?

Response: Although I am not currently a part of the Administration and cannot speak to the specifics of the agency's capacity, if I am confirmed, I commit to working closely with FDA staff to understand and address any such limitations.

27. Do you believe consumers have an adequate understanding of FDA's limited legal authority over cosmetics and the extent to which FDA monitors cosmetic products on the market?

Response: I look forward to learning the consumer's viewpoint of FDA's role in cosmetics. If confirmed I will prioritize transparent and effective communication with the American people.

Device safety

In 2015, I asked my Committee staff to investigate a series of dangerous infections at Virginia Mason hospital in Seattle linked to contaminated duodenoscopes. I issued a staff report in 2016 that linked this type of medical device to at least 25 different outbreaks of antibiotic-resistant infections that sickened at least 250 patients worldwide. These devices remain difficult to clean and can contribute to the spread of infections. My staff's report recommended that FDA expand post-market surveillance of medical devices to protect patients from infection. FDA has made some progress by committing new resources to develop and implement an active surveillance system using the National Evaluation System for health Technology (NEST), but we need to do more.

28. Will you make it a top priority to enhance monitoring of marketed medical devices, including fully leveraging the functions of NEST?

29. Will you insist on greater certainty about the risks associated with the use of devices before they are marketed?

Response to 28-29. If confirmed, I will carefully consider all tools for their ability to enhance accurate monitoring of the safety and effectiveness of marketed devices. I think it is important for FDA to take a proactive, not passive approach to upholding the gold standard for all medical products before and after they enter the market.

Dietary supplements

The dietary supplement market has grown exponentially over the past twenty years. Today, three out of every four consumers take a dietary supplement on a regular basis. Earlier this year, former Commissioner Gottlieb highlighted the widespread use of dietary supplements and announced a new plan to modernize dietary supplement regulation and product oversight to ensure product safety and quality. As part of this plan, Gottlieb acknowledged that a "mandatory listing requirement could provide significant benefits by improving transparency in the marketplace and promoting risk-based regulation" and "could also help facilitate efficient enforcement of the law and establish new mechanisms to identify bad actors who put the public at risk and undermine consumer confidence in the entire industry." According to the Pew Charitable Trusts, a product listing requirement would "enable FDA to direct its resources and expertise toward supplements with greater potential to harm consumers" and "enhance FDA's ability to respond effectively to emerging safety concerns."

30. Do you believe FDA needs to do more to oversee marketing of dietary supplements?

31. Will you continue to advance FDA's efforts to strengthen the regulation and oversight of dietary supplements?

32. Do you support a product listing requirement for dietary supplements?

33. What other authorities and resources does FDA need to help protect consumers, without imposing unnecessary burdens on companies that market safe, high-quality products?

Response to 30-33: So many Americans trust in the FDA to ensure the products they use are safe and effective. I have been pleased to see the new efforts surrounding the enhanced oversight of dietary supplement products, including the creation of the Office of Dietary Supplement Programs (ODSP), and the very recent announcement that the Botanical Safety Consortium (BSC) has been convened. I commit to continuing this work to modernize and enhance oversight of dietary supplements.

Drug supply chain
The U.S. drug supply chain is one of the safest in the world, but it has become more complex, in part because of increased globalization. Today, the majority of the active ingredients in drug products sold in the United States are manufactured in India and China. With this shift has come troublesome news about safety. A 2016 GAO report found that FDA lacks inspectional history for one-third of the foreign drug establishments in its catalog. This year, FDA announced millions of people had been exposed to possible carcinogens found in widely used, FDA-approved blood pressure and heartburn medications, like Zantac, manufactured in part by facilities in China and India. These reports raise concerns about the FDA's foreign drug inspection program, and the agency's ability to detect contaminants before drugs reach patients, wherever they are manufactured.
34. What actions will you take to ensure the drug supply is safe for patients in the United States?

Response: Thank you for your question. FDA's role is to ensure the safety of the drug supply. The U.S. has the safest drug supply in the world and if confirmed, I am committed to maintaining the safety of drugs and biologics used by the American people. According to recent testimony from FDA, as of August 2019, only 28 percent of the manufacturing facilities making APIs to supply the U.S. market were in our country. By contrast, the remaining 72 percent of the API manufacturers supplying the U.S. market were overseas, and 13 percent are in China. I believe advanced manufacturing could help to bring this manufacturing back to the U.S. If confirmed, I look forward to working with the staff at the FDA, along with partnering with Congress, ASPR, BARDA, the Department of Defense and others to address this issue and ensure that the U.S. drug supply remains safe.

35. On October 30, Dr. Janet Woodcock, Director of the Center for Drug Evaluation and Research (CDER) testified before the House Committee on Energy and Commerce's Subcommittee on Health that data available to CDER related to the manufacture of active pharmaceutical ingredients (APIs) have several limitations, including which API supplier a finished dosage form manufacturer is using at any given time. What authorities and resources does FDA need to improve the accuracy and completeness of information about API used in drugs marketed in the United States?

Response: If confirmed, I look forward to working with Dr. Woodcock and others at the FDA to determine what additional authorities FDA may need to address this issue.

FDA hiring

FDA officials and staff have long raised concerns about barriers to hiring and retaining the staff and expertise needed to keep pace with modern science and research. In 2016, the 21st Century Cures Act included provisions intended to improve hiring of premier talent at the FDA. Soon after, MDUFA IV authorized funding for CDRH to hire several new premarket reviewers. A 2017 FDA report found that FDA's hiring process would benefit from a comprehensive redesign and modernization effort and, in 2018, FDA launched a new public campaign to recruit and retain new employees. However, FDA continues to face hiring challenges and many positions remain unfilled at the Agency.

36. What steps will you take, if confirmed, to ensure FDA is fully staffed and able to meet its performance expectations?

37. Are there additional authorities that Congress could provide to FDA to assist with hiring and retaining staff, especially in key underrepresented disciplines (for example, providing additional pay authorities or greater flexibility to directly hire staff)?

Response 36-37: If confirmed, one of my top priorities on day one will be to ensure that all of the new authorities that were given to FDA through the 21st Century Cures Act are in fact being fully implemented. Nothing is more important than getting the right expertise in the agency to help keep our food safe, swiftly and safely bring cures to the American people, and fulfill the mission of the agency. We must be positioned to recruit and retain the best and brightest talent at the agency, and I look forward to working with Congress to making sure the FDA is fully staffed with the right people for years to come.

Food safety

Congress passed the Food Safety and Modernization Act (FSMA) in 2011, helping to protect public health and strengthen consumer confidence in our food supply. However, eight years later, the Agency still has not implemented parts of FSMA, and food-borne outbreaks remain a problem. For example, over the past two years, there have been four outbreaks of E. coli in romaine lettuce, resulting in 210 illnesses and 5 deaths. Just last week, FDA announced an investigation into incidents of illnesses caused by E. coli in packages of Caesar salad that contain romaine lettuce.

38. Your experience has been in the medical field, but FDA oversees the safety of 80 percent of the food supply. What actions will you take to ensure FDA fully implements FSMA and takes concrete steps to prevent food-borne outbreaks, including an effective food traceability system?

Response: You are right that there are areas of FDA regulation in which I have had less experience. I understand that FDA regulates around 20% of the U.S. economy – a large number. As a physician, I am very well versed in medical products oversight but I am not as familiar with FDA's programs related to food. That does not change my commitment to these programs, particularly because the US has the safest and most secure food supply chain in the world. I commit that, if confirmed, I will engage the professional staff at FDA across the Agency.

Drug pricing

As you know, patients and families around the country are concerned about the high cost of prescription drugs. FDA does not regulate drug prices, but it does have a role in increasing access to lower cost generics and biosimilars.
39. Please provide specific proposals of how you would target increased patient access to generics and biosimilars without sacrificing product safety, efficacy, or quality.

Response: High prescription drug prices and affordability are a significant problem and addressing this issue through a variety of means has been a priority of Congress, the Administration and the Department. I agree that strong action is needed. It's also important to ensure that whatever solutions we consider, do not have the unintended consequences of stifling innovation and the development of new medical products for the American people. There are indirect ways that FDA can assist in lowering prescription drug prices such as facilitating innovation and competition. As you know, FDA has a Drug Competition Action Plan and I look forward to working with Congress and career staff on this plan. I am particularly supportive of introducing more competition to help reduce drug prices including generic approvals, working to modernize and make more efficient the biosimilar pathway, and ensuring that there is transparency and a clear regulatory pathway, not game-playing in the generic and biosimilar spaces. I look forward to working with you on measures to reduce high prescription drug prices. I will make this a priority and do all that I can as FDA commissioner to ensure access of medical products for all Americans.

Nutrition
In March 2018, Former Commissioner Scott Gottlieb announced FDA's Nutrition Innovation Strategy. The strategy addresses a number of key agency actions to improve nutrition, including two-year short-term voluntary sodium-reduction targets for industry, and educational campaigns for menu labeling and the updated Nutrition Facts Label.
40. What are your priorities for improving nutrition?

Response: FDA plays an important role in promoting the nutrition of the country. If confirmed as Commissioner, I will use the best science to guide the appropriate steps related to sodium levels.

41. What are your specific plans to continue the progress on the Nutrition Innovation Strategy?

Response: I support FDA's efforts to promote the nutrition of the country, perhaps in ways that have not been considered previously. In all the decisions we make, we must follow the best and most current science and engage in stakeholders who can provide the necessary information to inform the best course of action.

42. What is your timetable for finalizing two-year sodium voluntary targets?

Response: I cannot speak to a timeline as I am not currently part of FDA. But I commit that, if confirmed, I will work expeditiously on the next steps.

43. What resources and activities do you plan to commit to educating consumers about menu labeling and the updated Nutrition Facts label?

Response: I cannot speak to a specific level of funding but I will commit, if confirmed, to prioritizing FDA's efforts around menu labeling and continuing to keep the Nutrition Facts Label requirements up to date.

Opioids

As an oncologist, you have mentioned the importance of holistic treatment while working on the front lines in pain management for patients who need it, while also balancing concerns of addiction. Substance use disorder (SUD) remains a deadly problem, and efforts are necessary across all areas of prevention, treatment and recovery. Research shows that medication assisted treatment (MAT) can be an effective part of treatment for opioid use disorder (OUD) and help sustain recovery. However, despite rising rates of opioid addiction in our country, millions of people still lack access to quality, evidence-based treatment for OUD, even with existing FDA-approved medications for OUD treatment, including buprenorphine, methadone, and naltrexone. Further, for people with other forms of SUD, options for MAT are even more elusive.

44. If confirmed, as Commissioner, how will you facilitate treatment options and the development of therapies to address SUD, including OUD, as a chronic disease?

45. How will you support development of options for MAT and address the challenges that remain in patient access and provider utilization of MAT as a key FDA priority in its response to the SUD epidemic?

46. This week, Public Citizen sent a letter to FDA requesting "a formal compliance investigation into an apparent clinical investigation conducted by California-based BioCorRx, Inc., and the Louisiana Department of Public Safety and Corrections that involved testing the effectiveness of sustained-release naltrexone implants — a formulation of naltrexone never approved by the FDA — for management of opioid and alcohol use disorders in prison inmates. The agency also should investigate whether BioCorRx has conducted or is currently conducting any similar clinical investigations." If confirmed, do you commit to immediately initiate an FDA investigation into this matter, including whether BioCorRx and the Louisiana Department of Public Safety and Corrections violated any applicable laws and regulations related to the protection of human subjects?

Response to 44-46: The opioid crisis is one of the largest and most complex public health tragedies that our nation has faced. This is a top priority for the Administration, the Department and Congress. It will be a top priority for me if I am fortunate enough to be confirmed. FDA was given important authorities by Congress in the SUPPORT act to assist in the prevention of misuse of opioids. Actions by FDA such as changes to packaging, labeling, the REMS program and efforts to stop the illegal importation of opioids are all important steps forward. I promise, if confirmed as FDA Commissioner, to make combating the opioid crisis a top priority of the agency and I look forward to continuing and enhancing those efforts, if I am fortunate enough to be confirmed. I am supportive of efforts to advance the development and use of safe and effective medication-assisted therapy or MAT. If fortunate enough to be confirmed, I will look into the specific issue that you refer to in question 46.

Pediatric devices

From 2008 to 2017, an average of only 24 percent of the total premarket approval (PMA) and humanitarian device exemption (HDE) application approvals in each fiscal year had an indication for a

pediatric population or subpopulation, and the majority of those pediatric indications were designated for children 12 years and older. The disparity in medical device innovation for adults and for children has led to unmet needs and difficulty in finding appropriate treatments for pediatric patients. Devices for adult indications may not be suitable for pediatric use because children are, among other things, often smaller and more active than adults. To address the lack of FDA-approved pediatric devices, FDA has pursued efforts such as funding consortia to provide seed funding and technical advice to sponsors of pediatric medical devices.

47. If confirmed, as Commissioner, how will you lead new and existing efforts to support the development and availability of safe and effective pediatric devices?

Response: I agree that there is a strong need to increase access to medical devices in the pediatric population, and recognize the unique needs of this population. If confirmed I commit to working with staff at FDA, stakeholders, and Congress to understand any challenges or barriers to bringing pediatric devices to market, and to advance policies and procedures that will spur progress in this space.

Shortages

The number of new drug shortages has increased after declining from a peak of 251 in 2011. There were 39 drug shortages in 2017 and 54 drugs shortages in 2018. Recent drug shortages include critical drugs such as hydromorphone, vincristine sulfate, immune globulin, and EpiPens. I applaud last month's release of FDA's Drug Shortage Task Force report, "Drug Shortages: Root Causes and Potential Solutions," which attempts to identify many of the root cause of shortages and offer policy solutions.

48. FDA's Task Force on Drug Shortages supports the concept of a rating system to incentivize manufacturer investment in quality management maturity for their facilities. What authorities and resources does FDA need to implement this type of rating system?

Response: I think the rating system you mention is an idea worthy of consideration. Before I can opine on the specific authorities and resources FDA would need, I would have to consult with the staff at FDA but I will commit to looking into this idea if confirmed.

49. On October 30, Dr. Janet Woodcock, Director of the Center for Drug Evaluation and Research (CDER) testified before the House Committee on Energy and Commerce's Subcommittee on Health that advanced manufacturing technologies can "improve drug quality, address shortages of medicines, and speed time-to-market" of medical products. If confirmed, how will you work with drug manufacturers to foster the adoption of advanced manufacturing technologies?

Response: I agree with Dr. Woodcock that advanced manufacturing could go a long way towards addressing drug quality and drug shortages. FDA should work together with regulated industry to speed up the adoption of this technology and there are a few specific actions I think they can take. For example, they can work closely with industry to tailor regulatory requirements so they are not over burdensome.

FDA's authority and science-based decision-making

FDA's gold standard and commitment to science over ideology are essential to continued public trust in FDA approved products.

50. If confirmed, do you commit to opposing efforts, legislative or otherwise, to limit FDA's authority to make decisions about the approval of safe and effective medication based on the best available evidence?

51. Do you believe FDA's ability to make scientific judgements about drug products and devices should be the same across all medical products?

Response to 50-51: Senator, I agree wholeheartedly that FDA represents the gold standard for protecting the public health and that these decisions must be based upon the best available evidence. It is trusted by all Americans and admired around the world for its mission of ensuring the safety, security, effectiveness of medical products and ensuring the safety of our nation's food supply. The professionals that FDA have remarkable expertise and a deep commitment to the agency's mission. I believe strongly in the importance of science, data and the law that have guided and continue to guide FDA in their decision-making across all medical and food products.

New drug development

Access to safe, effective contraception is essential to public health and women's health. Continued research is necessary to develop improved options for all people who choose to use hormonal drug products for both pregnancy prevention and non-contraceptive purposes. Clinical trials on new and emerging hormonal contraceptives should reflect the unique health needs of the wide range of individuals that use these products.

On July 12, FDA released draft guidance for industry that included recommendations for manufacturers to expand clinical trials for hormonal drug products to include people over the age of 35 or with a Body Mass Index over 30. Inclusive research will ensure new hormonal drug products better meet the needs of all patients who can become pregnant.

52. Do you agree it is critical to continue research on hormonal contraception to develop new and improved options and ensure safe, effective methods are available to meet individual needs and preferences?

53. If confirmed, how will you ensure that clinical research during the course of developing new hormonal drug products accurately reflects the needs of the wide range of people who can become pregnant?

Response to 52 and 53: Thank you for these questions. As you mention, the FDA recently issued a new draft guidance, "Establishing Effectiveness and Safety for Hormonal Drug Products Intended to Prevent Pregnancy." I believe it is important for the FDA to provide clarity to industry to advance the introduction of safe and efficacious drugs for consumers, including hormonal contraception.

Banning electric shock for people with disabilities

The Judge Rotenberg Educational Center (JRC) in Massachusetts is a specialized day and residential school for people with disabilities ages five though adulthood. The JRC, despite its mission of promoting "very effective education and treatment," uses electric shock to punish students. The practice has no evidence as therapy and has been found to be inhumane and harmful. In 2016, the FDA proposed to ban the device the JRC uses to shock people with disabilities. Unfortunately, the rule has not been finalized despite widespread public support to ban the practice.

54. If confirmed, will you commit to finalizing this critical rule and banning the electric shock of people with disabilities?

Response: I am committed to working with your office on this issue and working to protect American patients.

I look forward to working with FDA's professional staff to study this issue and understand the most efficient path forward that protects patients.

55. If so, please provide your proposed timeline for finalizing the rule, and if you believe the rule is on track with the FDA's fall agenda to be finalized by the end of 2019.

Response: I am committed to working with your office on this issue. I cannot speak to a proposed timeline, as I am not part of the administration yet an.